

6/ Declaration

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SUPPLEMENTAL
BROADENING REISSUE APPLICATION DECLARATION AND POWER OF ATTORNEY
BY THE INVENTORS

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and joint inventor of the subject matter which is described and claimed in patent number 6,004,582, granted December 21, 1999, and for which a reissue patent is sought on the invention entitled:

Multi-layered Osmotic Device

[] the specification of which is attached hereto.

[X] the Specification of which was filed on 12/03/2001 as Reissue Application Serial No. 10/004,772 and was amended on April 4, 2003 and August 18, 2003.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations § 1.56.

I verily believe the original patent to be wholly or partly inoperative or invalid, for the reasons described below:

1. by reason of having claimed less than I had the right to claim in the patent.
2. by reason of having failed to perfect the claim of priority in the patent.

At least one error upon which reissue is based is described as follows:

A) I failed to claim:

- 24) A multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:
- a) a compressed core comprising a first active agent and an osmotic agent for controlled and continuous release of the first active agent;
 - b) a semipermeable membrane surrounding the core and having a preformed passageway therein, said semipermeable membrane being permeable to a fluid in the environment of use and substantially impermeable to the first active agent;
 - c) an inert, completely erodible and/or water soluble polymer coat partially or completely surrounding the semipermeable membrane and plugging the passageway in the wall; and
 - d) an external coat comprising a second active agent for immediate release of the second active agent, an external coat comprising a second active agent for immediate release

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of the second active agent, wherein the osmotic device operates as follows in the one or more environments of use: the external coat partially or completely dissolves, erodes, swells and/or detaches from the osmotic device thereby releasing the second active agent and exposing the polymer coat; at least a portion of the polymer coat then dissolves and/or erodes thereby exposing the semipermeable membrane and the preformed passageway; the first active agent is then released from the core, such that the first and second active agents are released into the same or different environments of use to provide a controlled delivery of the one or more active agents.

- 25) A multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:
- a) a compressed core comprising a first active agent and at least one osmotic agent for controlled and continuous release of the first active agent;
 - b) a semipermeable membrane surrounding the core and having at least one preformed passageway therein;
 - c) an inert, completely erodible and/or water soluble polymer coat partially or completely surrounding the semipermeable membrane and plugging the passageway in the wall; and
 - d) an external coat comprising a second active agent for immediate release of the second active agent, wherein the osmotic device operates as follows in the one or more environments of use: the external coat partially or completely dissolves, erodes, swells and/or detaches from the osmotic device thereby releasing the second active agent and exposing the polymer coat; at least a portion of the polymer coat then dissolves and/or erodes thereby exposing the semipermeable membrane and the preformed passageway; the first active agent is then released from the core, such that the first and second active agents are released into the same or different environments of use to provide a controlled delivery of the one or more active agents.
- 26) A multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:
- a) a compressed core comprising a first active agent and at least one osmotic agent for controlled and continuous release of the first active agent;
 - b) a semipermeable membrane surrounding the core and having at least one preformed passageway therein;
 - c) an inert, completely erodible and/or water soluble polymer coat partially or completely surrounding the semipermeable membrane and plugging the at least one preformed passageway in the wall; and
 - d) an external coat comprising a second active agent for release of the second active agent, wherein the osmotic device operates as follows in the one or more environments of use: the external coat partially or completely dissolves, erodes, swells and/or detaches from the osmotic device thereby releasing the second active agent and exposing the polymer coat; at least a portion of the polymer coat then dissolves and/or erodes thereby exposing the semipermeable membrane and the preformed passageway; the first active agent is then released from the core, such that the first and second active agents are released into the same or different environments of use to provide a controlled delivery of the one or more active agents.
- 27) A multi-layered osmotic device for the controlled delivery of one or more active agents to

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one or more environments of use wherein the osmotic device comprises:

- a) a compressed core comprising a first active agent and at least one osmotic agent for controlled and continuous release of the first active agent;
- b) a semipermeable membrane surrounding the core and having at least one preformed passageway therein;
- c) an inert, completely erodible and/or water soluble polymer coat partially or completely surrounding the semipermeable membrane and plugging the at least one preformed passageway in the wall; and
- d) an external coat comprising a second active agent for immediate, rapid, delayed, slow, sustained, pseudo-first order, pseudo-zero order, timed, controlled or combination thereof release of the second active agent, wherein the osmotic device operates as follows in the one or more environments of use: the external coat partially or completely dissolves, erodes, swells and/or detaches from the osmotic device thereby releasing the second active agent and exposing the polymer coat; at least a portion of the polymer coat then dissolves and/or erodes thereby exposing the semipermeable membrane and the preformed passageway; the first active agent is then released from the core, such that the first and second active agents are released into the same or different environments of use to provide a controlled delivery of the one or more active agents.

Claim 24, as set forth above, is broader than claim 1 of the original patent in that claim 24 does not require the presence of the polymer poly(vinylpyrrolidone)-(vinyl acetate) in the inert completely erodible or water soluble polymer coat.

Claim 25, as set forth above, is broader than claim 1 of the original patent in that claim 25 does not specify the physical properties of the semipermeable membrane since such physical properties are detailed in the specification. Claim 25 also does not require the presence of the polymer poly(vinylpyrrolidone)-(vinyl acetate) in the inert completely erodible or water soluble polymer coat. Subsection d) of claim 25 does not specify controlled delivery of the first active agent, since that is already specified in subsection a).

Claim 26, as set forth above, is broader than claim 1 of the original patent in that claim 26 does not specify the physical properties of the semipermeable membrane since such physical properties are detailed in the specification. Claim 26 also does not require the presence of the polymer poly(vinylpyrrolidone)-(vinyl acetate) in the inert completely erodible or water soluble polymer coat. Subsection c) of claim 26 also requires "at least one" preformed passageway in the wall. Subsection d) of claim 26 does not specify controlled delivery of the first active agent, since that is already specified in subsection a). Subsection d) also does not limit the release profile of the second active agent.

Claim 27, as set forth above, is broader than claim 1 of the original patent in that claim 27 does not specify the physical properties of the semipermeable membrane since such physical properties are detailed in the specification. Claim 27 also does not require the presence of the polymer poly(vinylpyrrolidone)-(vinyl acetate) in the inert completely erodible or water soluble polymer coat. Subsection c) of claim 27 also requires "at least one" preformed

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passageway in the wall. Subsection d) of claim 27 does not specify controlled delivery of the first active agent, since that is already specified in subsection a). Subsection d) also expands the release profile of the second active agent to include "immediate, rapid, delayed, slow, sustained, pseudo-first order, pseudo-zero order, timed, controlled or combination thereof release of the second active agent".

- B) During prosecution of the application underlying the original patent for which a reissue patent is sought, the patentee failed to provide a certified copy and verified translation of the priority Argentine patent application below and therefore failed to perfect the claim for priority in the original patent.
- C) At least one of the claims of the original patent contains language that might be confusing. In particular, in column 23, line 18 of claim 1, the term "drug" refers back to the term "first active agent" in column 23, line 16, and in column 23, line 30 of claim 1, the term "drug" refers back to the term "second active agent" in column 23, line 29.

All errors corrected in this reissue application arose without any deceptive intention on the part of the applicant.

I hereby claim foreign priority rights under Title 35 U.S.C. §119 of any foreign application for patent or inventor's certificate on the invention listed below and have also identified below any foreign application for patent or inventor's certificate on the invention having a filing date before that of the application on which priority is claimed.

<u>P97 01 02351</u>	<u>May 30, 1997</u>	<u>Pending</u>
Application Serial No.	Filing Date	Status

As a named inventor, I hereby appoint Rick Matos, Reg. No. 40,082, as my agent with full power of substitution and revocation to prosecute this application and to transact all business in the U.S. Patent and Trademark Office connected therewith; and I request that all correspondence be directed to:

Rick Matos, Ph.D., Customer No.: 24,039
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that all calls be directed to (972) 747-7373; that all facsimile transmissions be directed to (972) 747-7375; and that all email messages be directed to innovarllc@shcglobal.net.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued

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thereon, or any patent to which this declaration is directed.

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